# What's News at the FDA in 2000

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# Overview

- Organizational Changes
- Food and Drug Modernization Act
- Reengineering
- Alternatives in 510(k)s
- Harmonization
- Division of Clinical Lab Devices
- Hot Topics in DCLD

# Organizational Changes

- David Feigal, M. D.-- Center Director
- Les Weinstein, J. D.-- Ombudsman
- Office Director-- vacant
- Deputy to Office Director-- new post

# Food and Drug Modernization Act (FDAMA)

- Interactive process for product review
- Decisive action
- Agency discretion, not mandatory requirements
- Codifies reengineering
- FDA review accountability/timeliness

# Reengineering

- New 510(k) Paradigm
- Product development protocol (PDP)
- Modular Premarket Approval Application review
- Standards

# Global Harmonization

Four study groups

- Regulatory Requirements/Premarket Review
- Device Vigilance/Post-Market Surveillance
- Quality System Requirements and Guidance
- Auditing

# Division of Clinical Laboratory Devices

- Core Program
- Alternatives to 510(k)
- Premarket Approval Application
- Guidance
- Hot Topics

# Core

- 510(K) Program
- 900 per year
- Diverse pool

# New Programs

- Special 510(k)s - 38/6 months
- Abbreviated 510(k)s - 5/6 months
- Third party reviews - 8/6 months

# New Programs

- Streamlined PMA
- Modular PMA
- Product Development Protocol

# Specific Guidance Documents

- Rapid Anti-Microbial Susceptibility Test
- Hepatitis C
- Drugs of abuse

# General Guidance Documents

- Labeling
- Data collection
- Over-the-Counter Collection Devices
- Available on FDA’s Medical Devices Home Page

# Hot Topics in DCLD

- Genetics
- Bioterrorism
- Least Burdensome
- CLIA

# Genetics

- What is the status quo?
- What options does FDA have to help?
- Can FDA offer oversight that will meet public health needs w/o impeding new technology?
- What are the potential costs to FDA with regards to resources?

# Bioterrorism

- FDA important contributor to U.S. response to potential threat
- Development of new vaccines, drugs
- Safeguards for the food supply
- Research for diagnostic tools
- Treatment of disease outbreaks

# Public Health Challenge

- Agents rarely encountered naturally
- Sometimes long incubation
- Agents may be genetically engineered
- Highly toxic nature of agents requires special equipment facilitates
- Need to expedite licensing and approval
- Regulatory process modified for emergency

# Public Health Challenge

- FDA to develop process to expeditiously license new vaccines, therapeutics, drugs and diagnostics
- FDA to develop methods to assure safety of regulated foods, drugs, medical devices
- FDA to acquire scientific expertise needed to support premarket review & research on new diagnostic products

# Least Burdensome Means to Market

- Required by FDAMA
- Applies to PMA, PDPs and 510(k)s
- Does not change standards for premarket review and approval
- Good science

# Least Burdensome is...

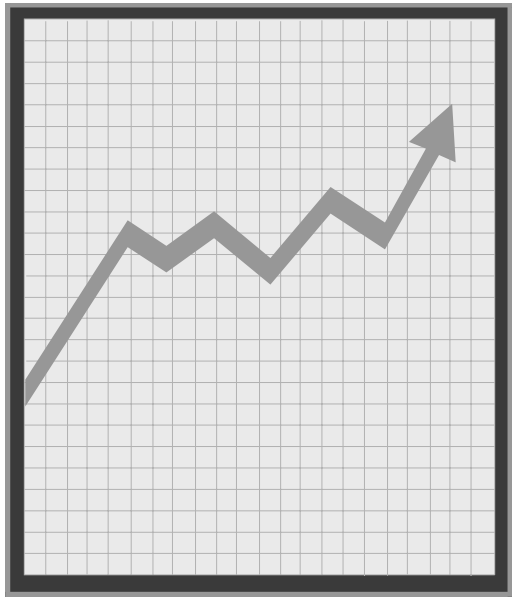
- A process, not a decision
- An opportunity to explore what data are available
- An opportunity to determine what data are needed
- A time to ask questions

# CLIA Categorization

- Week 13
- Categorizations
- FDA action on submissions
- Guidance
- Proposed rule
- Challenges
- Future

# Week 13

- Business is booming
- Overwhelming
- Backup, consultation by CDC



# Categorizations Performed on:

- 510(k) exempt test system
- Premarket Notification 510(k)
- Reagent/Instrument Applications
- Premarket Approval Application
- Humanitarian Device Exemption
- Class III Designation (FDAMA)
- Uncategorized test systems

# Total Number Categorized

- 400 moderate+High
- 45 waived
- 6 relabeling for waived

# How is a Test System Waived?

- Criteria for waiver in proposed Sept 13, 1995 rule
- Generic 9 waived by regulation
- Over-the-counter
- Prescription home use

# FDA Action on Submissions

- Manufacturers submit product applications to Document Mail Center
- Request for categorization are tracked in then Center’s database and the Division database
- Final signoff
- Categorizations are be subject to internal timelines

# FDA's Action (continued)

- Categorization enclosed with clearance letter, approval order or shortly after
- --or a separate letter with a or 510(k) exempt test system
- Categorization is effective as of the date of the written notification

# FDA's Action (continued)

- The complexity categorization will be put on FDA's CLIA home page.
- The information will include the document number, complexity, test system and the analyte
- For waived test systems, the information and Package Insert will be faxed to HCFA

# Publication of Categorizations

- Monthly on FDA's home page, start date May 2000
- Categorization linked to FDA's 510(k), PMA, HDE releasable database
- Federal Register Notice, interval to be determined

# Publication of Categorizations (continued)

- Proposal
- To review categorizations on Internet
- Send comments to Dockets Management
- FDA to publish responses to comments in the Federal Register

# Center for Biologics Evaluation and Research Test Systems

- Firm will submit all requests to CBER; CBER will send copy of procedure to Clara?DCLD for categorization and log-in to database
- DCLD will categorize 510(k), PMA, PLA test systems
- Complexity categorization will be performed by DCLD in consultation with CBER
- DCLD will notify the CBER-regulated firm of the complexity categorization by letter; categorization to be posted on FDA’s CLIA Home Page

# Sources of Information

- www.fda.gov/cdrh/clia.html
- Email: CLIA@CDRH.FDA.GOV
- CLIA Phone (301) 827-0496
- CLIA Fax (301) 827-1401

# CLIA Guidance

- Administrative Procedures for CLIA
- Waiver Checklists for Qualitative, Quantitative Test -reference method

# Proposed Rule

- Revisit the proposed rule on waiver
- May involve an open meeting to solicit comments
- Final rule

# Challenges

- Keep up the good work by CDC
- Remain consistent
- Establish benchmarks
- Make decisions in a timely manner
- Continue to interact with HCFA and CDC

# The Future

- Time of change
- Accurate and precise technology
- Smaller test system, multiple analyte
- DNA chip
- Monitoring, non-invasive, minimally invasive
- Job security